REMARKS

Applicants express the Applicants express their appreciation to the Examiner for conducting a telephone interview on January 28, 2005. During the interview, Applicants discussed with the Examiner the patentability issues raised by the Examiner in the Office Action mailed September 22, 2004. Claims 1-44 and 55 have been canceled. Claims 45 and 51-54 are amended. New claims 57-70 are added. Claims 45-54 and 56-70 are now pending in the application.

I. Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claims 45-54 and 56 under 35 U.S.C. §103(a) as being unpatentable over Waller (U.S. Pat. No. 5,800,539) in combination with Trotta et al. Cancer Research, 1981, Vol. 41, pages 2189-2196; and Spaner (U.S. Pat. No. 6,258,257).

Independent claim 45 as amended specifies a method for preventing or reducing the risk of developing graft-versus-host disease (GVHD) in a human patient who is a recipient of an organ or tissue transplant. The method includes administering to the transplant recipient pentostatin in a pharmaceutically effective amount of about 1-10 mg/m^2 or about 0.05-5 mg/m^2 within a predetermined time window before the transplantation. Support for the claim language "human patient" appears in the Specification, for example, at page 5, line 8; "1-10 mg/m^2" at page 6, line 11; and 0.05-5 mg/m^2 at page 35, line 4.

As discussed during the interview, Waller et al. discloses a method of administering drug-treated mononuclear cells to a transplant recipient. Cytotoxic chemotherapeutic drugs (e.g., mitomycin C, bleomycin, fludarabine, and doxirubicin (column 5, lines 1-15)) are used to render the cells incapable of proliferating and causing GVHD. Abstract; and column 4, lines 66-67; column 5, line 1. Thus, Waller does not teach or suggest administering pentostatin to a transplant recipient before the transplantation as specified in claim 45.

Trotta et al. discloses a study of immunosuppressive effects of constant infusion of 2'-deoxycoformycin (i.e., pentostatin or DCF) in mice. *See* Abstract. After the infusion with DCF, the mice were sacrificed and their tissues in lymphoid organs were analyzed. More specifically, Trotta et al. teaches that the mice were infused with DCF continuously at a constant rate of 0.4 mg/Kg body weight per day for 5 days. Page 2190, column 1, 3rd paragraph. For an adult patient

with body weight of 70 Kg and body surface area of 1.8 m^2 (or a pediatric patient with body weight of 35 kg and body surface area of 1 m^2) a dosage of 0.4 mg/Kg body weight equals 15 mg/m^2 approximately. Thus, Trotta not only fails to teach or suggest the claimed method of preventing GVHD in human patients by administering pentostatin within a predetermined time window before the transplantation, but also fails to teach or suggest administering pentostatin at the dose specified in claim 45. In addition, Spaner merely teaches that current methods to prevent and treat GVDH involve administration of drugs such as cyclosporin-A and corticosteroids (column 1, lines 49-53). Thus, none of the cited references, independently or in combination, teaches or suggests the claimed invention.

In view of this deficiency in the teaching or suggestion of the cited references, a prima facie case of obviousness has not been established under 35 U.S.C. §103(a). Withdrawal of this ground of rejection is therefore respectively requested.

II. New Claims 57-70

In the Examiner's Office Action mailed June 3, 2003, the Examiner states that claims 30-32 as originally filed are objected as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 30 as originally filed is directed to a method for preventing or reducing the risk of developing GVHD by administering a pharmaceutically effective amount of pentostatin a transplant recipient within a predetermined time window after the transplantation.

Applicants hereby submit a new independent claim 58 which is essentially the same as claim 30 rewritten in independent form including all of the limitations of the base claim and any intervening claims. Support for new dependent claims 59-69 can be found, for example, in dependent claims 21-26 and 33 as originally filed. Support for new claims 57 and 70 appears in the Specification, for example, at page 36, line 25. Thus, there is no new matter added to the new claims. Allowance of these claims is therefore respectfully requested.

CONCLUSION

In light of the remarks and arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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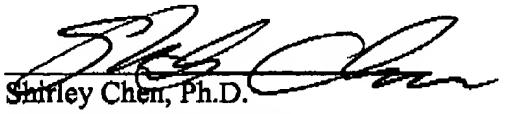
Date: January 28, 2005 By: 

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